REMARKS/ARGUMENTS

This is in response to the non-final Office Action mailed on February 21, 2008. No new matter is being added by the amendments made herein. Entry of this Response is respectfully requested.

1) Elections/Restrictions

Applicants acknowledge that the Restriction Requirement has been made final without traverse and that Group I (claims 1-5 and 10, drawn to detecting the presence of a CDP/Cux isoform comprising contacting a sample with an antibody) has been elected for consideration. Consequently, withdrawn claims 6-9 are herewith cancelled. Claims 1-5 and 10 have further been cancelled in favor of new claims 11-28 to better define the invention and adhere to the restrictions suggested by the Examiner.

2) Summary and explanations of the newly presented claims

Claims 1-10 have been cancelled without prejudice or disclaimer. Applicants reserve the right to pursue any subject matter removed by this amendment in one or more divisional applications.

Claims 11, 21 and 26 represent independent claims while claims 12-20, 22-25 and 27-28 are dependent. Claim 11 finds support in former claim 1. New claims 11, 21 and 26 make reference to "amino-terminally truncated" variants of CDP/Cux. Support for this terminology can be found from the disclosure as a whole and more particularly in paragraph **[0007]**, line 4; paragraphs **[0008]**, line 2; **[0010]**, and **[0012]**, line 3; and paragraph **[0026]** of the application as published. The location of the truncations (i.e., amino terminus) can be logically inferred from, for example, the descriptions of the DNA

binding domains contained in each amino-terminally truncated CDP/Cux polypeptide variants or explanations of how or where the truncations were generated or occurred. Further support can be found in paragraph **[0002]**, lines 17-19, which describe the presence of three Cut repeat domains (CR1 CR2 CR3) in full-length CDP/Cux proteins. Paragraph **[0004]**, lines 2-3, mentions that the "proteolytic cleavage of p200 generates CDP/Cux p110, which contains CR2CR3HD", or lacks the **amino-terminal** CR1. Further support is also found in paragraph **[0012]** which discusses different CDP/Cux isoforms and more particularly in the last two lines thereof; as well as in paragraph **[0013]** which describes the particular amino- terminally truncated p75 variant.

Independent claims 11, 21 and 26 refer to polypeptide variants of CDP/Cux comprising several characteristics that describe the invention. Further support for a polypeptide variant which is encoded by a nucleic acid produced from transcriptional initiation within intron 20 (I20) of the CDP/Cux locus [e.g., in claims 11 a), 21 a), and 26 a) ii) I)] can be found for example in paragraph **[0006]**, first sentence, which states, "A novel CDP/Cux isoform, p75, has now been found that is encoded by mRNA initiated within intron 20 of the CDP/Cux locus." A similar mention of transcription initiation in intron 20 is found in paragraph **[0012]**, lines 8-9 and in paragraph **[0013].** Additional support for a polypeptide variant which is encoded by a CDP/Cux mRNA comprising a translation start site within exon 21 [e.g., claims 11 b), 21 b) and 26 a) ii) II)] can be found for example in paragraphs **[0013], [0014] and [0015]**, first sentence, which states that the "I20 mRNA contains ... an open reading frame starting at the beginning of exon 21."

Support for amino-terminally truncated CDP/Cux polypeptide variants lacking Cut repeat domains CR1 and CR2 [e.g., claims 11 c), 21c), 26 a) ii) III)] and containing two DNA binding domains [e.g., claims 11 d), 21d), 26a) ii) IV)] which are Cut repeat domain 3 (CR3) and Cut homeodomain (HD) [e.g., claims 12 and 22] can be found in the disclosure as a whole. Further support can be found for example in paragraph **[0017]**, first sentence,

which states that "... CDP/Cux p110 isoform contains CR2, CR3, and HD while the p75 isoform contains CR3 and HD." Claims 13 and 23 find support in former claim 4.

Further support for claims 14 and 15 can be found in paragraph **[0008]** and more specifically in paragraph **[0018]**, lines 2-5; in paragraph **[0024]**, lines 1-3; and in paragraphs **[0034] - [0040]**. Claim 15 differs from claim 14 in that an antibody that binds to CDP/Cux polypeptides is used and that a determination of the size of the detected CDP/Cux variant is carried out. Further support for claim 15 is found in paragraph **[0015]** and in the above-mentioned paragraphs. Antibody, α1300, binds to the C terminus of CDP/Cux proteins and thus indiscriminately recognizes all claimed amino-terminally truncated CDP/Cux polypeptide variants. Additional support for a comparison to a known standard can be found in paragraph **[0042]**, lines 22-36, which gives several examples of possible known standards that can be used in the context of the present invention.

Further support for claims 16 and 18 can be found in paragraph **[0006]**, last sentence; paragraph **[0018]**, lines 1-14 and last sentence; and paragraph **[0020]**, lines 1-2 and 7-9. Additional support for claims 17 and 19 can be found in paragraph **[0024]**, lines 1-8.

Further support for claim 20 can be found for example in paragraph **[0025]**, and more particularly at lines 1-2 and 8-9; paragraph **[0034]**, lines 1-9; paragraph **[0040]**, lines 1-5; and paragraph **[0041]**, lines 1-5.

Further support for claims 21, 24 and 25 can be found in paragraph **[0037]** as a whole and more particularly in lines 7-19. Support for claims 26-28 can be found in former claim 10. Further support can also be found for example in paragraph **[0043]**.

3) Claim Rejections – 35 USC § 112

3.1 The Examiner has rejected claims 1-5 and 10 under 35 U.S.C. § 112, first paragraph, for "failing to comply with the written description requirement." While the Examiner acknowledges that the "applicants' seem to be only in possession of human CDP/Cux isoforms p200, p100, p110 and newly discovered p75", she mentions that the "written description is not commensurate in scope with the broadly claimed method encompassing a plethora of CDP/Cux isoforms yet to be discovered." In view of the instant amendments to the claims which now recite amino-terminally truncated CDP/Cux variants with defined characteristics, the Applicant respectfully submits that the disclosure clearly supports the genus covered by independent claims 11, 21 and 26 and, therefore, requests that the Examiner withdraws her rejection under 35 U.S.C. § 112, first paragraph.

3.2 The Examiner has also rejected claims 1-5 and 10 under 35 U.S.C. § 112, first paragraph, on the grounds that the specification does not reasonably provide enablement for the diagnosing and staging of cancer. The Examiner also indicates that the invention cannot be reasonably extrapolated as a method of determining the presence or stage of **any** cancer. As noted above, claims 1-5 and 10 have been cancelled. Newly presented claims 16-19 now recite a method of detecting a CDP/Cux variant and specify the forms of cancer to cancers found in breast tissue or blood, which are supported by the disclosure as filed. Claims 17 and 19 further specify the type of blood cancer as acute myeloid leukemia (AML), which is also supported in the specification. The Applicant respectfully submits that the current claims are fully enabled by the disclosure and, therefore, believes that the rejection under 35 U.S.C. § 112, first paragraph for lack of enablement has been overcome.

3.3 The Examiner has further rejected claims 1-5 and 10 under 35 U.S.C. § 112, second paragraph, on the grounds that: (a) Claims 1, 5 and 10 are vague and indefinite in the

recitation, "truncated CCAAT-displacement protein/Cut homeobox isoform"; and (b) "the claims do not note how the isoform is detected, nor which isoform" and thus do not "recite a *complete* method". The Applicant respectfully submits that in view of the deletion of the objected terminology, the now claimed amino-terminally truncated CDP/Cux polypeptide variants are clearly defined and, additionally, that the amended claims recite a complete method. In view of the above, the Applicant believes that the rejections under 35 U.S.C. § 112, second paragraph have been overcome.

In view of the above and foregoing, Applicant respectfully requests that the Examiner withdraws her rejections under 35 U.S.C. § 112, first and second paragraphs.

4) Claim Rejections – 35 USC § 102

4.1 The Examiner rejected claims 1-3, and 5 under U.S.C. § 102(b) as being anticipated by Moon et al., 2001 (Mol. Cell. Biol. 21(18): 6332-6345). As acknowledged earlier, said claims have been cancelled and replaced with new claims 11-28 that now specify amino-terminally truncated CDP/Cux polypeptide variants that are not taught by Moon *et al.,* 2001. Indeed, Moon *et al.*, 2001 does not teach an amino-terminally truncated CDP/Cux polypeptide variant that is, as recited, for example, in claim 11:

a) a variant which is encoded by a nucleic acid produced from transcriptional initiation within intron 20 of the CDP/Cux locus;
b) a variant which is encoded by a CDP/Cux mRNA comprising a translation start site within exon 21;
c) a variant which lacks Cut repeat domains CR1 and CR2;
d) a variant which contains only two DNA binding domains;
e) any combination of a)-d); or
f) a variant which is p75.

The Applicant therefore respectfully submits that the newly presented claims are not anticipated by Moon *et al.*, 2001.

4.2 The Examiner has also rejected claims 1-3 and 5 under 35 U.S.C. 102(a) as being anticipated by Moon *et al.*, 2002 (Int. J. Cancer 100: 429-432). The Examiner is referred to the arguments presented in 4.1 above, since Moon *et al.*, 2002 also does not teach the detection of any of the currently claimed amino-terminally truncated CDP/Cux variants.

In view of the above and foregoing, the Applicant respectfully requests that the Examiner withdraws her rejections of claims 1-3 and 5 under 35 U.S.C. 102(a) and 102(b).

5) Claim Rejections – 35 U.S.C. § 103

5.1 The Examiner rejected claims 1-3, 5 and 10 under 35 U.S.C. § 103(a) as being unpatentable over Moon *et al.*, 2001. Applicant notes that a *prima facie* case of obviousness has **only** been provided for the **kit claim** (former claim 10). It is, therefore, assumed that the rejection under 35 U.S.C. § 103(a) only applies to claim 10.

In view of the fact that neither Moon *et al.*, 2001 nor Moon *et al.*, 2002, teach or suggest the amino-terminally truncated CDP/Cux polypeptide variants recited in the present claims, it is respectfully submitted that new kit claims (26-28) should not be considered obvious. The same holds true for all pending claims, in view of the lack of any suggestions in the Moon references of the herein claimed polypeptide variants.

In view of the above and foregoing, the Applicant respectfully requests that the Examiner withdraws her rejection of claims 1-3, 5 and 10 under 35 U.S.C.§ 103(a).

CONCLUSION

In view of the above, it is submitted that the application and claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be resolved by telephone, the Examiner is invited to contact the undersigned at the telephone number shown below.